their lenses from their prescribing eye doctor—who obviously profits from each and every sale.

Over the years, I've introduced several bills to require the release of contact lens prescriptions. For the last several years, Representatives BURR, DINGELL, TAUZIN, WAXMAN, SCHAKOWSKY and I have been working together to fashion a bipartisan bill that can garner the support of a broad coalition to ensure its passage.

That day is here. I started out this effort with the support of Consumers Union and I'm pleased they have endorsed this version of the legislation as well. I'm also pleased that the American Optometric Association has been willing to come to the negotiating table and has also endorsed this final version of our legislation.

That tells you this is a good bill—we've got consumers and optometrists—the largest providers of contact lenses—agreeing that this day has come. It is time to update our consumer protection laws to ensure that contact lens wearers have the right to safely purchase their lenses from the provider that best meets their needs. Join us in support of H.R. 3140 to give consumers that right.

Ms. SCHAKOWSKY. Mr. Speaker, I yield 3 minutes to the gentleman from Utah (Mr. MATHESON).

Mr. MATHESON. Mr. Speaker, I rise to express my strong support for H.R. 3140, the Fairness to Contact Lens Consumers Act. I am pleased to have been an original cosponsor of this bipartisan legislation. It simply does the right thing for consumers.

This legislation will require eye doctors and optometrists to provide patients with a copy of their prescription for contact lenses, regardless of whether or not the patient asks for that copy. And the bill also requires that these prescribers to verify and provide a copy of the prescription to any person designated by the consumer to act on their behalf, such as third-party sellers.

What many people may not know, is that eye doctors have been required to provide patients with a copy of their prescriptions for eyeglasses since 1978, but the same requirement for some reason has not been in place for contact lens prescriptions. Today, with around 36 million Americans wearing contact lenses, ensuring that consumers are able to obtain their contact lens prescriptions and make a choice in where they purchase their contact lenses is simply the right thing to do.

I strongly support this bill and urge my colleagues to vote for it.

Ms. SCHAKOWSKY. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BURR. Mr. Speaker, I yield myself such time as I may consume to once again reiterate that this is a tremendous bipartisan effort that, as the gentleman from California (Mr. STARK) said, is well overdue, but this legislation is ripe today. I urge my colleagues to support it unanimously.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. OSE). The question is on the motion offered by the gentleman from North Carolina (Mr. BURR) that the House suspend the rules and pass the bill, H.R. 3140, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. MORAN of Kansas. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

REGULATION OF NONCORRECTIVE CONTACT LENS AS MEDICAL DEVICES

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2218) to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and for other purposes.

The Clerk read as follows:

H.R. 2218

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. FINDINGS.

The Congress finds as follows:

(1) All contact lenses have significant effects on the eye and pose serious potential health risks if improperly manufactured or used without appropriate involvement of a qualified eye care professional.

(2) Most contact lenses currently marketed in the United States, including certain plano and decorative contact lenses, have been approved as medical devices pursuant to premarket approval applications or cleared pursuant to premarket notifications by the Food and Drug Administration (''FDA'').

(3) FDA has asserted medical device jurisdiction over most corrective and noncorrective contact lenses as medical devices currently marketed in the United States, including certain plano and decorative contact lenses, so as to require approval pursuant to premarket approval applications or clearance pursuant to premarket notifications.

(4) All contact lenses can present risks if used without the supervision of a qualified eye care professional. Eye injuries in children and other consumers have been reported for contact lenses that are regulated by FDA as medical devices primarily when used without professional involvement, and noncorrective contact lenses sold without approval or clearance as medical devices have caused eye injuries in children.

SEC. 2. REGULATION OF CERTAIN ARTICLES AS MEDICAL DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following subsection:

''Regulation of Contact Lens as Devices

''(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

''(2) Paragraph 1 shall not be construed as having any legal effect on any article that is not described in that paragraph.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida (Mr. BILIRAKIS) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Florida (Mr. BILIRAKIS).

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to include extraneous material on H.R. 2218, the bill now under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

□ 1515

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 2218, which amends the Federal Food, Drug and Cosmetic Act to provide for the regulation of noncorrective contact lens as medical devices, and I commend the gentleman from Arkansas (Mr. BOOZMAN) for his work on this legislation.

As the corrective contact lens industry has grown, so has the practice of using noncorrective contact lenses for cosmetic purposes. Currently, there is very little regulation of these lenses. However, all contact lenses have significant effects on the eye and pose health risks if improperly manufactured or used without the supervision of a qualified eye care practitioner. Both corrective and noncorrective contact lenses have been approved as medical devices by the FDA. It just makes sense that the FDA should have the authority to regulate these lenses.

Mr. Speaker, having said that, I would urge all of my colleagues to support this important resolution.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, colored and patterned contact lenses can be a fun way to express one's sense of style. Noncorrective contact lenses that are manufactured responsibly and worn under the supervision of a qualified eye care professional are useful and a perfectly safe commodity.

For years, the FDA saw it that way too and properly classified colored contact lenses as medical devices. In fact, just over a year ago FDA issued an official notification noting that noncorrective contacts ''present significant risks of blindness and other eye injury if distributed without the involvement of a qualified eye professional.''

But in April, for whatever reason, and we have seen an FDA that has become more and more politicized in the last couple of years, but for some reason the FDA flip-flopped deciding that colored contact lenses were not medical devices and were instead cosmetics. This quiet, but important, policy change opened the door to a new public health threat.

By reclassifying colored contacts as cosmetics, FDA eliminated the requirement that these products be manufactured to exacting standards, that they be FDA approved for safety before marketing, and that they be labeled with directions for safe use. FDA has expressed concern about the safety of noncorrective lenses administered without a doctor's involvement. But FDA's decision to reclassify them in this increasingly politicized FDA, this decision to reclassify them eliminated its authority to require that very involvement.

Despite concerns raised by Members in the House, but more importantly by Prevent Blindness Ohio and other eye health advocates, FDA went ahead with this misguided plan. This bill corrects that mistake by statutorily reclassifying noncorrective contacts as medical devices by statute. This bill was carefully drafted to ensure that this would be its only effect, and it clearly states this change will have no limiting effect on FDA's discretion in classifying other products under the Food, Drug and Cosmetic Act.

H.R. 2218 enjoys bipartisan support in the Committee on Energy and Commerce. The chairman of the Subcommittee on Health, the gentleman from Florida (Mr. BILIRAKIS), and I have cosponsored this legislation, as have several other colleagues; and I am joined on the floor today by two other leading health advocates, the gentleman from California (Mr. WAXMAN) and the gentlewoman from California (Ms. ESHOO). I urge my colleagues to join us in supporting this important legislation in protecting the vision and health of American consumers.

Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Arkansas (Mr. BOOZMAN), who is himself an optometrist and certainly has lived with this problem for many, many years and knows the real world, and I thank the gentleman for bringing this to our attention.

Mr. BOOZMAN. Mr. Speaker, I thank the gentleman from Florida (Chairman BILIRAKIS) for yielding me this time.

I also thank the gentleman from California (Mr. WAXMAN) and his staff for working so hard on this bill. They have really gone above and beyond the call of duty in spending a great deal of time getting this to the situation that we have now. I also thank the gentleman from Florida (Mr. BILIRAKIS) for his help and the gentleman from Louisiana (Mr. TAUZIN).

Today we have the opportunity to close a loophole that has caused harm to many people young and old throughout the country. The loophole is a quirk in the law that allows decorative, plain old contact lenses to be sold without a prescription. Although this may not sound like a big deal, as a practicing optometrist for over 25 years, it is.

There are many cases of damage caused by contact lenses sold without the supervision of an eye care professional. Take, for instance, the case of a 14-year-old girl who purchased a pair of decorative contact lenses from a local video store and received no instructions on how to care for them. She ended up suffering a severe bacterial eye infection, and ultimately had to have a corneal transplant, which is a very significant surgery. Or the 32-year-old man who bought a pair of lenses at the local flea market for a Halloween costume. Again, the customer was provided with no directions at all on proper usage. He was later diagnosed with a corneal abrasion. He had scratched his eye because they did not fit his eye. He was later in a situation that resulted in possible permanent loss of vision.

Unfortunately, there are many, many more people whose vision has been compromised because of this type of contact lens being available to the general public without the supervision of eye care professionals. It is important to know that although adults are affected by the availability of these lenses, our children are the most vulnerable. As all of us who have children know, reason is often overruled by the desire to be fashionable and trendy.

Selling lenses to change one's eye color in video stores, flea markets, hair salons, and gas stations is inviting trouble and, frankly, should not be allowed.

A simple eye infection is the least of problems with unsupervised contact lens use. The worst is it can lead to permanent blindness. Proper care of the lenses and instructions on the correct way to use them are the keys to preventing these afflictions. Consumers are not getting this information from the video store clerk or the gas station attendant.

H.R. 2218 presents a simple fix to a dangerous problem. This bill is not intended to address the complicated legal issues surrounding intended use. The gentleman from California (Mr. WAXMAN) and I have worked hard to ensure that the language in this bill remains neutral on this question, and I think we have succeeded.

Additionally H.R. 2218 is being endorsed by the health care community, including the American Optometric Association and the American Academy of Ophthalmology, as well as the leading manufacturers in the contact lens industry and consumer protection groups.

Mr. Speaker, I cannot stress strongly enough that unregulated, unsupervised use of decorative contact lenses is extremely hazardous to one's health. H.R. 2218 would simply close that loophole that allows these lenses to be sold unregulated. I would strongly encourage my colleagues to support H.R. 2218.

Mr. BROWN of Ohio. Mr. Speaker, I yield such time as he may consume to the gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. Mr. Speaker, I thank the gentleman for yielding me this time.

I am very pleased to be able to join my colleagues in urging support for a bill that deems all contact lenses to be medical devices under the Federal Food, Drug and Cosmetic Act; and I thank the gentleman from Arkansas (Mr. BOOZMAN) for his leadership in sponsoring this legislation. Anyone who has any doubts about how significantly contact lenses affect the structure and function of the eye need only spend a few minutes talking with the gentleman from Arkansas (Mr. BOOZMAN), who, by virtue of his professional training, understands these dangers better than anyone else in the House of Representatives.

This bill is urgently needed. All contact lenses pose serious health risks. Lenses the wrong size can deprive the surface of the eye of oxygen. Lenses worn for too long can cause painful ulcerations of the cornea. Lenses that are poorly manufactured or misused can become contaminated and cause vision-threatening infections. Until recently, FDA had the tools to control the risks of contact lenses. They considered all lenses of all types to be Class III medical devices. Using its medical device authority, the FDA required that companies follow good manufacturing standards, obtain approval prior to marketing, report adverse events promptly, and sell their lenses only with a prescription from an eye care professional.

However, under FDA's current interpretation of the law, some contact lenses are now considered cosmetic, nonmedical devices. These lenses, which the agency refers to as decorative lenses, are colored or feature unusual designs. These lenses pose exactly the same health risks as other lenses, yet today these lenses only have to comply with requirements for cosmetics, and there are very few requirements and they are difficult to enforce.

Treating them in this way, I believe, is a recipe for disaster. Lenses sold outside the protections of medical device laws have caused numerous eye injuries. It is critically important that FDA have the ability to stop these dangerous sales as quickly and efficiently as possible. The solution is simple: treat all contact lenses as medical devices. No contact lenses should be classified in the same category as lipstick.

H.R. 2218 would ensure that all contact lenses are treated the same as medical devices. This bill is enforced by professional associations representing ophthalmologists and optometrists, by leading manufacturers and by consumer groups. It is a basic consumer protection, and it is common sense.

Finally, let me say this bill has been written with the understanding and agreement of all parties that it should not be interpreted as either a rejection or a ratification of the legal arguments

underlying FDA's decision to treat noncorrective lenses as cosmetics. For that reason, the bill includes a rule of construction stating that the bill should not be construed as having any effect on any product regulated by the FDA other than the specific contact lenses at issue here. I thank the gentleman from Ohio and the distinguished chairman of the Subcommittee on Health, and I join with every Member who has spoken on this bill in urging support for it.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. OSE). The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the bill, H.R. 2218, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes.''.

A motion to reconsider was laid on the table.

FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Monahan, one of its clerks, announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 2297. An act to amend title 38, United States Code, to improve benefits under laws administered by the Secretary of Veterans Affairs, and for other purposes.

The message also announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S. 1156. An act to amend title 38, United States Code, to improve and enhance provision of health care for veterans, to authorize major construction projects and other facilities matters for the Department of Veterans Affairs, to enhance and improve authorities relating to the administration of personnel of the Department of Veterans Affairs, and for other purposes.

PEDIATRIC RESEARCH EQUITY ACT OF 2003

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 650) to amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

The Clerk read as follows:

S. 650

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pediatric Research Equity Act of 2003''.

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

''SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

''(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

''(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

''(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

''(2) ASSESSMENTS.—

''(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

''(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

''(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

''(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

''(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

''(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

''(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

''(A) the Secretary finds that—

''(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

''(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

''(iii) there is another appropriate reason for deferral; and

''(B) the applicant submits to the Secretary—

''(i) certification of the grounds for deferring the assessments;

''(ii) a description of the planned or ongoing studies; and

''(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

''(4) WAIVERS.—

''(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

''(II) is not likely to be used in a substantial number of pediatric patients.

''(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

''(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

''(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

''(iii) the drug or biological product—

''(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

''(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

''(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

''(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

''(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

''(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

''(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

''(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

''(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

''(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

''(2) WAIVERS.—

''(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to